Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

- 1. (previously presented) A pharmaceutical composition consisting essentially of fexofenadine or a pharmaceutical acceptable acid addition salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition.
- 2. (original) The composition according to Claim 1, wherein the salt of fexofenadine is fexofenadine hydrochloride.
- 3. (original) The composition according to Claim 1, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 1 wt. % to about 80 wt. %, based on the total weight of the pharmaceutical composition.
- 4. (original) The composition according to Claim 3, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 5 wt. % to about 50 wt. %, based on the total weight of the pharmaceutical composition.
- 5. (original) The composition according to Claim 4, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 20 wt. % to about 35 wt. %, based on the total weight of the pharmaceutical composition.
- 6. (original) The composition according to Claim 1, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 10 mg to about 200 mg.
- 7. (original) The composition according to Claim 6, wherein the amount of fexofenadine or pharmaceutical acceptable salt thereof is from about 30 mg to about 180 mg.
- 8. (original) The composition according to Claim 1, wherein the lactose is selected from the group consisting of lactose monohydrate, lactose anhydrous, α -lactose, β -lactose, and combinations thereof.
- 9. (original) The composition according to Claim 8, wherein the lactose is lactose monohydrate.
- 10. (original) The composition according to Claim 1, wherein the amount of lactose is from about 25 wt. % to about 65 wt. %, based on the total weight of the pharmaceutical composition.

- 11. (original) The composition according to Claim 10, wherein the amount of lactose is from about 50 wt. % to about 60 wt. %, based on the total weight of the pharmaceutical composition.
- 12. (original) The composition according to Claim 1, wherein the low-substituted hydroxypropyl cellulose when dried at 105 °C for 1 hour contains 5-16% of hydroxypropoxy groups.
- 13. (original) The composition according to Claim 12, wherein the low-substituted hydroxypropyl cellulose when dried at 105 °C for 1 hour contains 10-13% of hydroxypropoxy groups.
- 14. (original) The composition according to Claim 13, wherein the low-substituted hydroxypropyl cellulose is selected from the group consisting of: LH-11 having a hydroxypropoxy content of 11% and an average particle size of 50 microns; LH-21 having a hydroxypropoxy content of 11% and an average particle size of 40 microns; LH-31 having a hydroxypropoxy content of 11%, and an average particle size of 25 microns; LH-22 having a hydroxypropoxy content of 8%, and an average particle size of 40 microns; LH-32 having a hydroxypropoxy content of 8%, and an average particle size of 25 microns; LH-20 having a hydroxypropoxy content of 13%, and an average particle size of 40 microns; and LH-30 having a hydroxypropoxy content of 13%, and an average particle size of 25 microns.
- 15. (original) The composition according to Claim 14, wherein the low-substituted hydroxypropyl cellulose is LH-21 or LH-11.
- 16. (original) The composition according to Claim 1, wherein the low-substituted hydroxypropyl cellulose is present in an amount of from about 2 wt. % to about 25 wt. %.
- 17. (original) The composition according to Claim 16, wherein the low-substituted hydroxypropyl cellulose is present in an amount of from about 3 wt. % to about 15 wt. %.
- 18. (currently amended) A method of preparing a pharmaceutical composition consisting essentially of fexofenadine or a pharmaceutical acceptable acid addition salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition, said method comprising:
 - (a) mixing fexofenadine, lactose, <u>and low-substituted hydroxypropyl cellulose</u>, and optionally one or more excipients to form a premix;
 - (b) adding a solvent and optionally a surfactant to the premix formed in Step (a) to form a wet granulation; and
 - (c) drying the wet granulation to form dried granules; and
 - (d) optionally milling the dried granules; and

- (e) (d) mixing at least one excipient with the dried granules to form a pharmaceutical composition.
- 19. (currently amended) A method of preparing a pharmaceutical composition consisting essentially of fexofenadine or a pharmaceutical acceptable acid addition salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition, said method comprising:
 - (a) mixing fexofenadine, lactose, <u>and low-substituted hydroxypropyl cellulose</u>, and optionally one or more excipients to form a premix;
 - (b) adding a solvent and optionally a surfactant to the premix formed in Step (a) to form a wet granulation; and
 - (c) drying the wet granulation using a tray dryer to form dried granules; and
 - (d) optionally milling the dried granules using a low shear mill; and
 - (e) (d) mixing at least one excipient with the dried granules to form a pharmaceutical composition.
- 20. (original) The method according to Claim 19 wherein the low shear mill is a conical screen mill.